

Notice of Allowability

Application No.

10/702,149

Examiner

Andrew B. Freistein

Applicant(s)

DOW ET AL.

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Amendment filed 1/10/2007.
2. ☒ The allowed claim(s) is/are 1, 2, 4, 6, 7, 8, 10, 11, 16, 17, and 24 (now 1-11).
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

DETAILED ACTION

The amendment filed 1/10/2007 was entered. Claims 1-11 and 14-24 are pending. Claims 12 and 13 were cancelled.

Restriction Requirement

As a result of the amendment filed 1/10/2007, the product claims are deemed allowable and the method of treatment claims are rejoined. Applicant reserves the right to file one or more divisional applications on withdrawn product claims.

Claim Rejections - 35 USC § 112

Claims 12 and 13 were rejected under 35 U.S.C. 112, first paragraph. Claims 12 and 13 were cancelled and the rejection is moot.

Examiner's Amendment

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given during a telephone interview with Attorney Julie Lappin on February 12, 2007.

This application has been amended as follows:

1. In claim 1, in lines 11-12 of the claim, after, "hydrogen, (C₁-C₆)alkyl, or taken together with R⁸ or R⁹", delete, "is -CH₂CH₂- or -CH₂C(O)-;" , and insert --to form a morpholine or morpholin-3-one;--.
2. In claim 16, delete, "The method of Claim 15" , and insert

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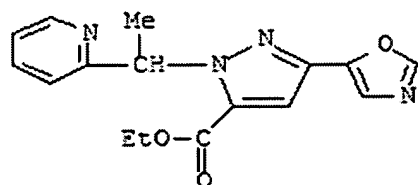
--A method for treating a disease, condition or disorder modulated by a cannabinoid receptor antagonist in animals comprising the step of administering to an animal in need of such treatment a therapeutically effective amount of a compound of Claim 1, a pharmaceutically acceptable salt thereof, or a solvate or hydrate of said compound or said salt,--.

3. In claim 16, in line 3 of the claim, after, "depression" , delete, "atypical depression,".
4. In claim 16, in lines 4-5 of the claim, after, "disorders, psychoses, schizophrenia," , delete, "behavioral addictions, suppression of reward-related behaviors,".
5. In claim 16, the last line of the claim, delete, "gastrointestinal disorders,".
6. In claim 17, after, "The method of Claim" , delete "15" and insert "16".
7. Cancel claims 3, 5, 9, 14, 15, 18, 19, 20, 21, 22 and 23.

Reasons For Allowance

The instant invention is a compound of formula (I), a pharmaceutical composition comprising a compound of formula (I) and a method of treating a disease modulated by a cannabinoid receptor antagonist.

The closest relevant art is: Lin et al., US Pat. No. 5,470,862, which discloses the



compounds:

(see col. 29, Table 1, 9th listed compound on

page). The instant invention differs from Lin et al. in at least two respects. First, in the instant invention, L is defined to be C(R⁴)(OR⁵) and R⁵ is taken together with R⁸ or R⁹ to

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form a morpholine. Lin et al. discloses an oxazole in this position. Secondly, in the instant invention R^2 and R^3 each independently represent $(CH_2)_n$ -aryl or $(CH_2)_n$ -heteroaryl groups, whereas the compound disclosed in Lin et al. has a $C(O)OCH_2CH_3$ moiety in the R^2 position.

The instant invention is also enabled to treat a disease modulated by the cannabinoid receptor antagonist, because similar pyrazole and imidazole compounds have been shown to treat similar diseases. For example, Rimonabant (a pyrazole compound) was successfully tested in humans as treatment for obesity and smoking cessation. Cannabinoid receptor antagonists and agonists shows promising results for treating drug dependence, cognitive disorders, and physiological functions such as feeding, appetite, pain, memory, learning and motor coordination. See Muccioli et al., "Synthesis and Activity of 1,3,5-Triphenylimidazolidine-2,4-diones and 1,3,5-Triphenyl-2-thioxoimidazolidin-4-ones: Characterization of New CB1 Cannabinoid Receptor Inverse Agonists/Antagonists," J. Med. Chem., Vol. 49, pp. 872-882 (2006); see also Lallemand et al., "SR147778, a CB1 Cannabinoid Receptor Antagonist, Suppresses Ethanol Preference in Chronically Alcoholized Wistar Rats," Alcohol, Vol. 39, pp. 125-34 (2006); see also Ramirez et al., "Prevention of Alzheimer's Disease Pathology by Cannabinoids: Neuroprotection Mediated by Blockade of Microglial Activation," J. Neuroscience, 25(8), pp. 1904-1913 (2005).

Telephone Inquiry

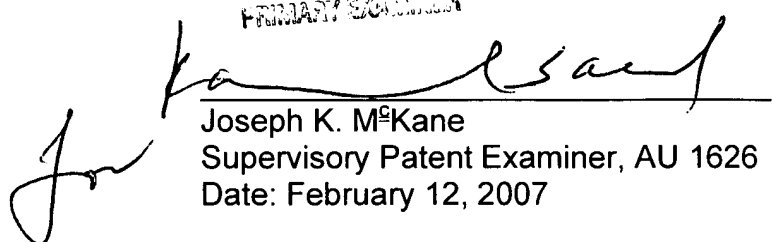
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew B. Freistein whose telephone number is (571) 272-8515. The examiner can normally be reached Monday-Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph M^{re}Kane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free).

Andrew B. Freistein
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KAMALA BATES, PH.D.
PATENT EXAMINER



Joseph K. M^{re}Kane
Supervisory Patent Examiner, AU 1626
Date: February 12, 2007